Subpart F—Availability of Information

§ 316.50 Guidance documents.

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the FEDERAL REGISTER. A request for a copy of the list should be directed to the Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

[78 FR 35135, June 12, 2013]

§ 316.52 Availability for public disclosure of data and information in requests and applications.

(a) FDA will not publicly disclose the existence of a request for orphan-drug designation under section 526 of the act prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Upon final FDA action on a request for designation, FDA will determine the public availability of data and information in the request in accordance with part 20 and §314.430 of this chapter and other applicable statutes and regulations.

(d) In accordance with §316.28, FDA will make a cumulative list of all orphan drug designations available to the public and update such list monthly.

(e) FDA will not publicly disclose the existence of a pending marketing application for a designated orphan drug for the use for which the drug was designated unless the existence of the application has been previously publicly disclosed or acknowledged.

(f) FDA will determine the public availability of data and information contained in pending and approved marketing applications for a designated orphan drug for the use for which the drug was designated in accordance with part 20 and §314.430 of this chapter and other applicable statutes and regulations.

PART 317—QUALIFYING PATHOGENS

Sec.

AUTHORITY: 21 U.S.C. 355f, 371.

SOURCE: 79 FR 32480, June 5, 2014, unless otherwise noted.

§ 317.1 [Reserved]

§ 317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

The term ''qualifying pathogen'' in section 505E(f) of the Federal Food, Drug, and Cosmetic Act is defined to mean any of the following:

(a) *Acinetobacter* species.
(b) *Aspergillus* species.
(c) *Burkholderia cepacia* complex.
(d) *Campylobacter* species.
(e) *Candida* species.
(f) *Clostridium difficile*.
(g) *Coccidioides* species.
(h) *Cryptococcus* species.
(i) Enterobacteriaceae.
(j) *Enterococcus* species.
(k) *Helicobacter pylori*.
(l) *Mycobacterium tuberculosis* complex.
(m) *Neisseria gonorrhoeae*.
(n) *Neisseria meningitidis*.
(o) Non-tuberculous mycobacteria species.
(p) *Pseudomonas* species.
(q) *Staphylococcus aureus*.
(r) *Streptococcus agalactiae*.
(s) *Streptococcus pneumoniae*.
(t) *Streptococcus pyogenes*.
(u) *Vibrio cholerae*.